10/04/2012

Comment	Response	Policy Change
Topic 1 - Sufficiency of potential water contaminant list of CECs.		
Michael J. Plewa, Ph.D.		
Incorporating an evaluation of mixtures may provide a more accurate description of the potential risks of the chemicals present in recycled water before and after treatment processes.	In general, staff agrees with this suggestion. However, a detailed evaluation of mixtures was outside the charge of the Science Advisory Panel (Panel). Potential risks associated with mixtures are addressed in the prioritization scheme proposed by the Panel.	None
Richard M. Gersberg, Ph.D.		
There is no rationale or analyses presented in either document on the existing degree of public health risk posed by the presence of CECs after surface spreading and direct recharge scenarios, and because of this, the benefit of public health risk reduction by the requirements of this new Final Draft Amendment are not only unknown, but they cannot be compared to the current regulatory approach by the CDPH which consists of both a treatment technique and also a certain CEC monitoring requirements.	Staff disagrees with this comment. The prioritization scheme developed by the Panel and described in the Panel Report does provide the rationale to assess the health risk from remaining CECs in product water of surface spreading and direct injection projects. The Panel was not charged to assess the existing degree of public health risk for individual groundwater recharge projects that have been permitted by CDPH. The relative risk assessment for these groundwater recharge projects have been published in a recent National Research Council report on water reuse (NRC 2012). In addition, of interest for this commenter would be a separate peer reviewed chemical risk assessment conduced on the OCWD/OCSD Groundwater Replenishment System	None

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	(EOA, 2000).	
Karl G. Linden, Ph.D.		
It is not clear that the final list of CECs (Table 1) of the draft amendment includes any additional studies beyond those reviewed by the Panel.	The CECs listed in Table 1 were recommended by the Panel and are based on studies reviewed by the Panel. The Panel suggested that a review of the CECs listed in Table 1 should occur every three years considering CEC monitoring results as well as additional occurrence and toxicological information that is available at that time.	None
The specific chemical/physical characteristics of the chemical (i.e. K_{OW}, K_H etc.) and what family of CECs this chemical represented with regard to these physiochemical or biodegradable characteristics is not clearly discussed or reported in either the Panel Report or the draft amendment.	The specific physicochemical and biodegradable characteristics are not discussed in detail in the report, because the rationale is described in detail in peer-reviewed journals and final reports that are readily accessible and citied in the Panel Report (mainly Drewes et al. 2008, 2010 a, b; Dickenson et al. 2009).	None
Removal of CEC across the types of treatment processes. Since AOP are part of the treatment train recommended in California, it is also important to address transformation projects, such as oxidation byproducts. While these transformation projects as	The Panel Report stresses the importance to address the risk from transformation products. The Panel stated that for "unknown unknown" CECs, bioanalytical and chemical screening methods should be employed to quantify effects or equivalent concentrations and identify chemicals for	None

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noted as "unknown knowns" by the Panel, it could be argued that they should be "unknown unknowns" as the combination of background water constituents, CECs, and oxidation could form not just breakdown products (which may be considered unknown knowns), but also new products that would not necessarily be recognizable from a known parent compound.	which there is the greatest urgency in developing MEC and MTL data for further assessment" (Panel Report, pg. 60). Staff agrees with the reviewer that some by-products after AOP treatment could be classified as "unknown unknowns".	
The list of CECs should also include information on the range of physiological and biodegradable characteristics of these chemicals to illustrate that list is indeed broad enough to cover a range of both performance and health based chemicals of similar structure and function. Furthermore, it is important to note that changes in water quality such as pH and possibly organic matter characteristics can affect the physiochemical properties of some chemicals and therefore impact the removal performance and health-based impacts. Such water quality inducted changes, is known for the CECs selected, should be reported, and may be indicated by characteristics such as pka.	As stated in the Panel Report and Attachment A of the draft policy, the CECs selected are only suitable for two types of groundwater recharge, surface spreading (practicing SAT) and direct injection (employing RO/AOP). The indicator CECs represent different degrees of biodegradability (for SAT) or rejection/oxidation properties for RO/AOP. Staff strongly agrees that the suggested removal efficiencies (see Table 6) only apply if key boundary conditions are fulfilled, as specified in footnotes of Tables 5 and 6.	None

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Imma Ferrer, Ph.D.		
Agree that the CCL3 list is not inclusive of a diversity of monitoring data that has been collected in California, especially pharmaceutical compounds, thus should only be a guide in the selection process.	Acknowledged.	None
It is not clear how all these lists (CCL3 from EPA, UCMR and CDPH lists) were taken into account in the Panel Report. In Sections 4 and 5, only those CECs for which measured environmental concentrations (MECs) were available were considered for the calculation of monitoring trigger levels (MTLs). And from those, only the ones exhibiting a ratio of MEC/MTL higher than 1 were considered health CECs. This is a limited view of what is out there in the environment and what are the important issues to be addressed.	The process is explained in the Panel Report in Sections 4 and 5. Initial MTLs were derived from drinking water benchmarks using seven different sources (See Appendix J of the Panel Report.) regardless whether MECs were available or not. In a second step, MEC data were compiled for representative recycled water qualities in California and applied to the selection framework. It was the intent of the Panel to develop a short list of CECs that have a health- or performance-based relevance rather than measuring any CEC because some laboratory can.	None
The Panel stated that concentrations of degradation products in recycled water that occur have not yet been quantified. I personally know of many studies (including USGS and NAWQA data) that report these types of degradation products in surface and groundwater in the state of California.	Staff agrees with the reviewer that certain degradation products in recycled water have been identified. The results of these studies have been considered in the selection process. Since all of these studies are using rather specific analytical methods established by certain research	None

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Maybe some of these lists should have been used for the selection process as well.	labs, commercial methods are not available yet for their quantification. Thus, none of these chemicals made it on the short-list.	
The unknown unknowns in Section 2 of the Panel Report are a bit ambiguous since there are no data, not even an example of what these types of compounds can be. Moreover, when using terms such as "unknown unknowns" and "known unknowns" it would be helpful to see a reference to the author who first reported and defined these terms in a peer review Journal: *James L. Little, Identification of "Known Unknowns" Utilizing Accurate Mass Data and Chemical Abstracts Service Databases , Journal of the American Society for Mass Spectrometry, vol. 22, 348-359.*	The terminology the Panel used was adopted and defined in the context of the universe of chemicals that potentially can be present in recycled water. The reference the reviewer is suggesting was not considered in these discussions and was published in 2011 after the Panel Report was released.	None
Overall, I think there are sufficient water contaminant lists that have been considered here. However, it would be helpful to have some of the proprietary and relevant environmental lists that a few scientists have reported in the last few years in well-known peer reviewed	The Panel was charged to develop an approach that would allow the selection of CECs for monitoring programs of recycled water in California based on their health-relevance or suitability to assess treatment performance for certain processes rather than assembling a list of CECs because	None

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journals, as well as extensive USGS environmental monitoring programs.	certain laboratories measured them in environmental monitoring programs.	
Michael D. Collins, Ph.D.		
The development of bioanalytical techniques suggested by the Panel for three compounds (1, 2, 3-trichloropropane, hydrazine, quinolone) that should be monitored to establish MECs were not included in the amendment.	Some facilities in California are currently collecting this data. Results so far are not showing concentrations above the MTLs. Staff, therefore, did not consider it necessary to include a special monitoring program for these constituents in the proposed amendment.	None
Prokaryotic toxins were not mentioned in the Panel Report. This category of compounds includes cyanotoxins that could develop secondarily as a result of the nutrient load from wastewater that is released to holding ponds prior to groundwater recharge. The Reviewer is not sure if these compounds could be of concern (perhaps if nutrient-rich wastewater was released into holding ponds that were able to support cyanobacteria), but it is certain that the wide diversity of different compounds in this category are probably not well represented by the compounds chosen for monitoring.	Cyanotoxins were discussed among the Panel members. The Panel concluded that there is a low concern that cyanotoxins would form in surface spreading operations and if so, would not survive SAT and ending up in product water.	None

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Inorganic compounds (boron, chlorate etc.) are not included. Lithium might also be a chemical of concern based on its use as a pharmaceutical agent at relatively high dosages.	Inorganic chemicals that are already regulated in California (such as boron, chlorate, etc.) were not considered CECs.	None
In addition to biological endpoints, some general chemical screens of either gas chromatographic or liquid chromatographic separations coupled with mass spectrometry should be used to attempt to determine the number of unknowns in recycled water (and some preliminary idea of the relative quantities of the unknowns).	Staff agrees with the reviewer regarding the need to agree on a wider range of meaningful biological endpoints of concern and to couple bioanalytical screening tools with chemical analysis to potentially identify relevant CECs that are causing a response. This approach is considered in the selection framework proposed by the Panel (see Figure 8.1, p. 59, Panel Report).	None
Stanley B. Grant, Ph.D.	Response	Policy Change
The approach described in Section 2 of the Panel Report for selection of the Universe of CECs builds upon a procedure developed by the EPA in consultation with the National Research Council, and appears reasonable, tailored to issues involving the use of recycled water in California, and scientifically justified.	Acknowledged.	None

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Topic 2 – Appropriateness of approach for selecting CECs of toxicological relevance to monitor in recycle water uses.		
Michael J. Plewa, Ph.D.		
Exposure to a toxicant might potentially be altered by the presence of other toxic agents in which interactions can be additive, synergistic, or antagonistic. Single chemical approach can potentially miss yet to be characterized components and important biological effects resulting from chemical interactions.	Staff agree sin principal. This uncertainty is captured through safety factors that were applied in deriving the MTLs similar to EPA's approach in deriving drinking water MCLs. In addition these interactions may be measurable through the bioanalytical assays proposed.	None
Richard M. Gersberg, Ph.D.		
There is no cogent rationale presented for why the health indicator (particularly caffeine and triclosan) were chosen in health indicators, and not good quantitative relationships (as in statistical correlations) could be found in the supporting literature to show that the behavior of the performance indicators chosen is generalizable and well correlated to the whole universe of CECs.	The rationale for how these chemicals were selected as health-based indicators is provided in detail within the Panel Report. As stressed in the Panel Report, it provides a framework and utilizes the data sources cited. Following this framework and using the cited data, triclosan and caffeine emerge as health indicators. Again, this is explained in detail within the Panel Report. The Panel has recommended that California should review literature periodically and update the list as needed. Performance indicators do correlate with CECs having similar physicochemical and biological properties rather than the whole	None

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	universe of CECs. References to support these correlations are provided in the Panel Report.	
Karl G. Linden, Ph.D.		
Agree with the Panel's comment that predominantly negative findings of epidemiological and other toxicological studies provide concordant evidence that recycled water is a safe source of water for drinking water supplementation. It is also prudent to assume that the lack of heretofore-positive findings does not negate the need to continuing monitoring recycled water for safety.	Acknowledged.	None
The reviewer does not have a concern with the approach for selecting MTLs. The approach for comparing CEC 90th percentile MEC to the MTL and for selecting candidates for monitoring was sound. Agree that only CECs with robust analytical methods should be selected for monitoring. However, priority should be made for any CEC that meets thresholds for monitoring, but does not yet have a robust method.	Staff agrees that priority for robust analytical method development should be given to CECs that meet toxicity thresholds.	None

Comment	Response	Policy Change
Imma Ferrer, Ph.D.		
Compilation of data. The compilation of data itself of CEC occurrence seems well done and results are clearly shown in the Panel Report. It is interesting to note that no halogenated pharmaceuticals (which would be expected to have more toxicity) were included in previous monitoring programs. This pre-selection was made from a narrow list that did not include many of the potential contaminants that could be present in municipal wastewater. I think other resources, such as USGS or EPA monitoring data, could have been considered here to expand the scope of CECs. Specific comments are included under other issues.	Staff agrees that the pool of CEC occurrence data that was considered by the Panel to populate a monitoring list using the proposed selection framework is limited. To the best of the Panel's knowledge, there were no USGS and EPA studies available for Title 22 recycled water in California during the time of data compilation.	None
Assignment of a toxicologically relevant concentration level Concentrations reported in Figures from Appendix K (ng/L) were not specified anywhere in the Panel Report. It would be useful to report the screening level ADIs for each one of the compounds reported in Tables 5.1 and 5.2. As shown it is a bit confusing how those levels were achieved.	Concentrations reported in Appendix K are in ng/L. The drinking water benchmarks (ADIs) were compiled in Appendix J. The focus of Section 5 was on occurrence (MECs). However, Tables 5.1 and 5.2 also list the MEC/MTL ratio to give an indication of health relevance.	None

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Assignment of a toxicologically relevant concentration level What are the units for MTL's? As presented in Eq. 4.1 of the Panel Report and taking the example for 17ß-estradiol presented, the units are ug/L. Later in Table 5.2, it seems that the units are ng/L for MTL's, but it does not mention it specifically.	The unit of MTL can be ug/L or ng/L. Examples of the calculations are given in Table 5.1. For the calculation of the MEC/MTL ratio, the units need to be similar.	None
Assignment of a toxicologically relevant concentration level There are a lot of assumptions about potential toxicity of a given CEC and the ADI values derived from different sources (or drinking water benchmarks). In some cases (e.g. DEET, ibuprofen, triclosan…) the derived MTL values vary a lot. Taking the most conservative values might not be the best choice to include or not to include a specific contaminant in the monitoring lists.	Staff agrees with this comment. However, the Panel used a transparent and conservative approach and selected the most conservative value published in the studies considered.	None
Assignment of a toxicologically relevant concentration level It was difficult to understand why the MTL for caffeine is so much lower than atenolol or fluoxetine. Likewise, a value of 350000 (0.35 ppm) for bisphenol A or a value of 500000 (0.5ppm) for 4-nonylphenol, both of which have been previously reported as	The calculation for MTLs is provided in detail within the report. As stated in the Panel Report, Panel utilized a limited number of studies for the numerical values used for toxicity data due to the scope and resources available. The Panel	None

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carcinogenic compounds/endocrine disruptors by several studies, seems unreasonable to me. The model used here is a cancer/toxicological model, but does not take into account endocrine disruption at very low levels of concentration (1-10 ng/L) that has been proven in several studies (Kidd et al. 2007). Using a cancer/toxicological model, pharmaceuticals (prescribed for human intake) are automatically excluded from the CEC list, because the doses at which they are prescribed are high enough that the MTL level will always exceed the MEC level monitored; so in a way this pre-selection is somehow exclusive of important CECs that are present in the environment and could potentially be endocrine disruptors or developmental disruptors for infants (e.g. brain function).	recommended that State of California add their own toxicity data to the framework should they find a particular study relevant to their needs. However, Panel suggests that Kidd 2007, a study on fish reproduction, is not likely a wise choice for basing human health decisions.	
Assignment of a toxicologically relevant concentration level Table 5.3 in the Panel Report. In the column where it says "available analytical method", what different sources were investigated? For example, there is an EPA method for alachlor OA and other EPA methods as well as for the majority of the organophosphate	This list of contaminants was provided to major contract laboratories within the State of California. Each lab was asked to indicate yes or no for each of the chemicals. When all labs answered "no", this was reflected as a "no" in the report.	None

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compounds included in this list. Moreover, why did the Panel decided not to recommend gathering MEC information for most of them? I think it would be important to gather MEC for some of the high use pesticides (e.g. alachlor, terbufos, etc.) in California, as well as recognize that there are available analytical methods (official and non-official) for most of the compounds shown in this list.	Conversely, a single laboratory responding "yes" would result in "yes" in the Panel Report under analytical methods available. This project was to consider recycled water, not agricultural run-off. Pesticides are regulated in the State of California and therefore weren't considered CECs.	
Comparison of the MEC to the MTL. The MTL is based on several factors including toxicity and intake volume. If MEC is higher than MTL then a compound is considered potentially toxic and becomes a candidate for monitoring. But this calculation does not take into account synergistic effects, such as sum of related CECs (anti-depressants, hormones, endocrine disruptor compounds…) in the same parcel/volume of water. I think that in certain cases the MTL is a value that will work to trigger specific potential health risk compounds, but as a whole picture scenario it might be too limited and it might not reflect the real environmental potential risk. My final comment here is that MECs and MTLs were compared for a selected list of	Staff agrees with this comment. The approach is chemical by chemical. The toxicity of mixtures should be captured through appropriate bioanalytical screening tools targeting appropriate endpoints. Staff agrees that the list of CECs recommended for monitoring is limited and shouldn't be considered final. The Panel developed a science-based approach for selection and utilized the rather limited initial occurrence data set to populate a recommended monitoring list for CECs in recycled water.	None

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compounds that were included in previous monitoring programs (Section 5). So, again, the scope is narrowed to only include these analytes and does not consider other relevant environmental contaminants that are present in recycled municipal wastewater.		
Evaluation of robust analytical method availability. The Panel did not include names of the CECs that were excluded because the Panel considered that they did not have commercially available analytical methods. Also, were these methods based on U.S. EPA guidelines? It is not clear how this issue can be reviewed if only limited information is available in the Panel Report. Furthermore, not much has been described in the Panel Report related to analytical methodologies for the identification/determination of environmental contaminants, other than in Section 7.3. The use of high resolution-mass spectrometry techniques would be an invaluable addition to the described instrumentation, especially for the identification of newly and relevant non-target/unknown contaminants (Ferrer & Thurman, 2009). I would encourage the	The issue of robust analytical methods is discussed in Section 7 of the Panel Report. As stated in section 7.5, approved analytical methods meeting the requirements were developed by the USEPA, other government agencies, universities, consensus methods organizations, water laboratories, and instrument manufacturers. Section 7 did provide references that specify additional details for analytical methods.	None

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Panel to comment more specifically about the different analytical approaches that can be used and are currently used for the detection of environmental contaminants. Note: Ferrer has several suggestions on analytical method to use for CECs (see specific comments).		
Evaluation of robust analytical method availability. In Table 5.3 many of the compounds shown do have an available analytical method for their determination. This should be clarified, if the Panel meant there is no EPA method or there is no official method whatsoever.	The Panel didn't imply that no analytical method exist for the CECs listed in Table 5.3, but no commercial methods (meeting the requirements as specified in Section 5) were available for these CECs.	None
Evaluation of robust analytical method availability. I want to emphasize one of the sentences used by the Panel in the Panel Report: *"A monitoring program truly is only as good as the reliability of the data collected"*. Totally true and I would even add that the monitoring should be performed with the best analytical tools available at present.	Acknowledged	None

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Michael D. Collins, Ph.D.		
Compilation of data. A significant amount of effort should be attributed to determining the vast number of contaminants that are found in water and developing analytical techniques to measure the concentrations of the compounds in aquatic systems. Because this is such a large task, it would be beneficial to coordinate efforts to perform this process with other agencies that may be interested in this data such as the U.S. EPA and the U.S. Geological Survey as well as other states that are interested in determining the purity of drinking water as well as recycled water.	Staff agrees with this comment. This effort by far exceeds the capabilities of a single regulatory agency, such as the State Water Board.	None
Compilation of data. Using information regarding the amount of various contaminants that are purchased and estimating the amount that could find their way into wastewater would be a difficult exercise in prediction, but may yield information that would be valuable in prioritizing analytical development approaches. This approach could use information regarding the environmental half-life of chemical substances as well as data on the human half-life and various physicochemical parameters to	Staff agrees with this comment. Members of the Panel have successfully applied the Predicted Environmental Concentration (PEC) approach previously.	None

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hypothesize which compounds should be detectable in aquatic environments, and then subsequent studies could verify the predictions.		
Assignment of toxicologically relevant concentration level. It does not seem appropriate to refer to the MTL as a toxic level. The MTL is actually derived from the allowable daily intake (ADI) of the compound, and consequently is probably more appropriately defined as a safe level of a specific contaminant. Clearly, ADIs are designed to describe a biological response of the general population, and there will be instances where genetic susceptibilities will make an individual sensitive to an agent that is non-toxic to the general population.	The Panel defined the MTL as "monitoring trigger level" rather than "toxicity level".	None
Assignment of toxicologically relevant concentration level. The proposed process for calculating the MTL is to use the screening level allowable daily intake (ADI) to calculate the MTL. The Panel Report (2010) describes large variability (a factor of 2000-fold) in the ADI for 17β-estradiol. This same issue is mentioned later in the Report (Section 8.2)	The rationale of the approach is explained in the Panel Report. The Panel chose to use the lowest value available as a conservative approach. The California OEHHA value also was used by the US EPA for the development of CCL3 as the trigger point for a "list" decision (as is reflected in the dossier publically available for E2).	None

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where it is stated that the reason that the MEC to MTL ratio exceeded 1.0 for 17β-estradiol was because the MTL was based on data from the California Office of Environmental Health Hazard Assessment (OEHHA) cancer slope factor as opposed to the ADI developed by the World Health Organization (WHO). Such a lack of consistency in the calculated MTLs undermines the entire process of creating an MEC to MTL ratio as the primary parameter for determining the course of action for a contaminant.		
Comparison of the MEC to the MTL. Using a ratio of environmental concentrations (MEC) to concentrations of concern (MTL) seems logical to the Reviewer. It also seems logical that the Science Advisory Panel Report (2010) states that in the absence of environmental concentrations, prioritization of compounds will be on those agents that are the most potent (defined as compounds with an MTL less than or equal to 500 ng/liter).	Acknowledged.	None

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Concerns on the risk assessment approach The proposed approach uses the therapeutic dose equivalently to the lowest observed adverse effect level (LOAEL), thus assuming a therapeutic index of 1.0. However, the therapeutic index is vastly different for pharmaceutical agents (and is probably available from the US Food and Drug Administration). For example, the therapeutic index for the opioid analgesic reminfentanyl is 33,000 to 1, whereas the cardiac glycoside digoxin has an index of 2 to 1. Is this just a conservative assumption?	Yes	None
Concerns on the risk assessment approach. The rationale for increasing the uncertainty factor by an order of magnitude for non-genotoxic carcinogens and endocrine disrupting compounds seems somewhat arbitrary. Are the effects of these categories of toxins at low doses more problematic than neurotoxins whose damage may accumulate over a lifetime or immunotoxins that induce a hypersensitivity reaction after a previous exposure?	The decision process for analytical method determination is provided above.	None

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Evaluation of robust analytical method availability. It would be a valuable perspective to know which CECs were removed from consideration because of the lack of commercially available, robust analytical methods. Furthermore, it would be informative to further divide this list of compounds into those that do not have a robust analytical method (a scientific issue) and those for which an appropriate analytical method is just not commercially available (a non-scientific issue). For pharmaceutical agents, for example, it is not clear to the Reviewer why there would not be a robust analytical method, unless the method exists for a biological matrix but requires an extraction procedure for aquatic concentrations.	Staff agrees with the reviewer that additional work is needed to refine the list of meaningful CECs for monitoring, which underscores the recommendation to charge a follow-up Panel with a periodic review.	None
Stanley B. Grant, Ph.D.		
The approach described in Sections 4 and 5 of the Panel Report for selecting CECs of toxicological relevance builds on published approaches (specifically that described in Snyder et al., 2010), and is clear, logical, and scientifically justified. Several minor considerations include: (1) ADIs are	(1) ADI should be defined as "acceptable daily intake". (2) SF stands for "safety factor" (3) Comment noted on swimming exposure. Staff concurs with comment on reliance of noted references and the Panel has done	None

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variously defined as "allowable daily intakes" and "acceptable daily intakes" (page 30); (2) Relative to Fig. 4.2, "SF" is not defined in the Panel Report glossary; (3) The discussion of swimming ingestion rates on page 33 seems out of place. Perhaps the authors should stick to the discussion of the more relevant Cooper and Olivieri, 1998; Sakaji et al., 1998; and Ottoson and Stenstrom, 2003 studies; (4) it would be helpful to know more about the survey instrument employed to obtain information on the CEC monitoring data, and more specifics on the response rate (page 37). In the absence of such information, one might be concerned that the results are not representative; (5) Figure 5.1, please include units on the vertical axis.	so as part of approach and development of recommendations. (4) The unit should be ng/L.	

Topic 3 – Determination of initial monitoring trigger levels for landscape irrigation.

Karl G. Linden, Ph.D.		
I have no disagreement with the approach.	Acknowledged.	None
Imma Ferrer, Ph.D.		
It is well explained in the Panel Report how MTLs are developed for landscape irrigation. Just a note: in Tables 5.1 and 5.2 the difference between potable reuse MTLs and irrigation MTLs is a factor of 10, not a 100 as described in page 34 of the	The concentrations listed under "irrigation" are 100 times larger than those assumed for potable consumption, since two liters (2000 mL/day) per day is assumed for potable and 20 mL/day is assumed for irrigation.	None

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Panel Report. However, I cannot imagine that drinking 5 ppm (or is it 50 ppm?) of 4-nonylphenol in a swimming pool or irrigation canal is safe.		
Michael D. Collins, Ph.D.		
The assumption that exposure to recycled water through landscape irrigation is one percent of drinking water ingestion (20 ml per day) seems to be a reasonable assumption. Thus, the MTLs for landscape irrigation are 100 times higher than the MTLs for potable reuse. Although there are rare scenarios where it may be imagined that children or naïve individuals may exceed this consumption limit, it seems reasonable to calculate a conservative consumption value based on these events.	Comment noted.	None
Stanley B. Grant, Ph.D.		
The reliance on Cooper and Olivieri (1998), Sakaji et al. (1998) and Ottoson and Stenstrom (2003) seems reasonable. Although as noted above, the discussion of swimming ingestion rates appears out of place and irrelevant to this discussion (page 33).	Acknowledged.	None

Comment	Response	Policy Change
Topic 4- Adequacy of the selected performance indicators CECs		
Karl G. Linden Ph.D.		
There is no discussion on the range of properties that CEC indicator chemicals have in either document. Therefore, without looking into the literature, it is not possible to know if the properties of the chemical to serve as indicators represent the universe of CEC of interest for California. It would be helpful if these properties and some discussion on them and how they represent the CEC universe were included somewhere for the public.	Please see responses above. Staff believes that the indicator CECs recommended for monitoring are representative to assess the performance (and health relevance) of two groundwater recharge practices (surface application and direct injection) rather than the entire universe of CECs.	None
Adequacy of the elected performance indicators would necessitate an understanding of the extent to which these chemicals were removed in the proposed treatment processes for reclaimed water. Specifically, performance information for membrane treatment and UV-advanced oxidation would be included in the Panel Report. However, some of the information is in the reference material.	The specific information regarding the fate of performance based indicator CECs is provided in the peer-reviewed literature which is citied in the Panel Report.	None
Based on pilot and full-scale studies (Drewes et al. and Dickenson et al.) following RO treatment, antenolol, trimethoprim, gemfibrozil and	The Panel does not expect any of the indicator CECs recommended for RO/AOP processes other than NDMA to be present after RO treatment. NDMA is listed both as	None

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meprobamate were noted as good performance indicators of UV/H_2O_2 AOP. Note that this is only specified for when UV/H_2O_2 processes follow RO – those chemicals that remained in the water portion – RO were the only ones that could be tested. Another good indicator noted was NDMA. NDMA is a good indicator for UV photolysis, not necessarily for AOP in UV/H_2O_2 process, but this is not pointed out anywhere in the Panel Report.	health- and performance based indicator.	
Disagree with the statement "The absence or removal of an indicator constituent during a treatment process would also ensure that absence of removal of unidentified chemicals with similar properties." The absence of one compound ensures the absence of other chemicals because it is possible that the indicator compound was never there and if no other similar compounds were monitoring for, you cannot say that other compounds with similar properties would also be absent.	The suggested approach recommends an initial baseline monitoring that confirms the presence of suggested indicator CECs in the feed water. If the presence is confirmed the statement holds true, if not, other suitable indicator CECs need to be selected. The proposed amendment has been revised to require an alternative indicator CEC to be added to the monitoring program if an indicator s found not to be present in the feedwater.	Edit is included in the change sheet.
Imma Ferrer, Ph.D.		
DEET is a good indication, however it sorbs strongly onto surfaces and there is	Staff agrees.	The reporting limit has been increased to 50 ng/L (0.05 µg/L).

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some carryover with DEET in methods. Thus, a LOD of 1 ng/L is probably not possible because of carryover issues and a more reasonable value would be 20-30 ng/L based on our current work. This compound is very easy to monitor and detect by either GC-MS or LC-MS with solid phase extraction for sample preparation.		
Pesticide should be included on the list, since pesticide applications are used in CA in urban and landscape settings. The triazines are used and detected in both groundwater and surface water in CA. I strongly urge the state to consider adding the two triazines, atrazine and simazine, along with the two soil degradates, deisopropylatrazine and deethylatrazine, to their monitoring list of CECs. They are toxic compounds with USEPA limits of 3 ug/L and 2 µg/L, respectively. Although not strictly CECs, they would be quite useful in monitoring treatment facilities in California. Finally, I would point out that DEET is not a pesticide as such, but an insect repellant used on humans.	Simazine and atrazine were considered, but available data did not show concentrations in recycled water above threshold levels. The use of DEET is acknowledged.	None
Gemfibrozil would be a good indicator	Acknowledged. The reporting level	None

Comment	Response	Policy Change
compound for the general class of lipids known as fibrates. It is relatively easy to monitor for; however, it gives only one good MRM transition for LC-MS-MS, making it somewhat difficult to have a good secondary ion for confirmation at low levels, i.e. 1-10 ng/L.	provided in the Panel Report is 10 ng/l.	
Iopromide does not represent any other compounds or pharmaceuticals; thus, I consider it of limited value as an indicator compound. It is a poor choice because of difficulty of analysis. I would suggest other more common pharmaceuticals to take its place, such as a common over-the-counter medication, such as one of the analgesics, i.e. ibuprofen or diclofenac, with diclofenac my favorite choice based on analytical methodology and ease of detection and widespread use. Diclofenac has been reported in 18 samples with a median of 22 ng/L (Appendix K).	Iopromide represent CECs with a rather large molecular weight (>700 Dalton). It occurs at concentration higher than most pharmaceuticals and can be used as tracer of wastewater impact. Diclofenac was not selected as a performance indicator because of a commonly low occurrence level in recycled water in California.	None
Based on my experience, sucralose is present in wastewater at relatively high levels, hundreds of ng/L and is always present. It is not a tracer of wastewater, based on my experience, because it is used in many foods and drinks, as well as	Staff disagrees with this comment. Sucralose is an excellent indicator for wastewater impact and recommended as a performance indicator. For RO/AOP processes, a high removal is expected. In SAT projects, sucralose can be used to	None

Comment	Response	Policy Change
excreted; thus, it has multiple sources and falls into the same basket as caffeine. It is a bad choice for a monitoring program as an indicator compound since it, like caffeine, is consumed by the public in large quantities. For the sake of aesthetics, it is a bad choice and does give credence to water quality studies when it is one of the major monitored compounds. Sucralose does not represent a family of compounds, except of course for sucrose, which does not make any sense. I also don't see the point of using this compound as a performance indicator for treatment purposes since its removal is less than 25%.	estimate dilution with native groundwater.	
Michael D. Collins, Ph.D.		
The validity of this list of compounds as indicators of treatment performance will eventually depend on the complete inventory of compounds in recycled water (a constantly changing compendium of compounds) and the capacity of the performance indicators to predict or mimic the other compounds. The Reviewer does not have any better suggestions for compounds on this list, but thinks that the process should be flexible as data is	Acknowledged.	None

Comment	Response	Policy Change
collected and analyzed. The question is whether there are compounds in recycled water that are not removed by the various unit operations that are currently in place. If such compounds exist, then presumably the performance indicator CECs would fail to predict the fate of such compounds.		
Stanley B. Grant, Ph.D.		
Section 8.3 is written clearly, and the basis for distinguishing between indicators and surrogates well described. The basis for selecting specific indicator CECs (Table 8.2) could have be better articulated. Also, the symbols delta X and delta Y need to be defined in the text. I gather delta X represents the removal of surrogates, while delta Y represents removal of indicators, but this was not clear.	The symbols delta X and delta Y are defined as a differential as indicated in the equations provided in each column; one represents surrogate parameter and the other one indicator CECs.	None

Topic 5 – Adequacy of the selected surrogates for monitoring treatment process performance.

Richard M. Gersberg, Ph.D.		
More evidence showing that the behavior of the chosen surrogates correlated well to the behavior of the whole universe of CECs is needed, especially at the low ppt level.	This information is provided in the peer-reviewed literature as referenced in the Panel Report (2010).	None
Karl G. Linden, Ph.D.		
More information should be provided as to	The surrogate parameters and indicator	None

Comment	Response	Policy Change
what surrogates are good for what treatment process; otherwise they may be used incorrectly. Section 8.3 in the Panel Report touches on this issue and prescribes a process to determine which indicator compounds and surrogates may be important to monitor, but it does not explicitly state the appropriateness of each indicator or surrogate for monitoring the operational performance of a treatment.	CECs are specific to two groundwater recharge practices in California. The Panel was not charged to develop lists of surrogates and indicators for any water treatment process.	
"Performance indicator CECs and surrogates detected during the baseline phase and that exhibited reduction by a unit process and/or provided an indication of operational performance shall be selected for monitoring of standard operations." While this is generally a logical approach, this logic suggests that only some of the performance indicators may be monitored over time, depending on what is found in the baseline phase. It is conceivable that those compounds detected during the baseline phase that are selected for study are not ideal indicators for a specific treatment process. There may want to be some specific compounds that are known to be good indicators for a specific treatment process (such as NDMA	Correct. The baseline monitoring phase is intended to confirm the presence of suggested indicator CECs. If none of the suggested indicator CECs is present, the project proponent needs to consult with the State Water Board/CDPH to find a suitable substitute. NDMA is included as a performance indicator for direct injection projects.	Edits made to sections 3.2 and 3.3.

Comment	Response	Policy Change
for UV/H_2O_2) to be required for longer tern monitoring, even if they are not selected from the base line monitoring phase.		
Imma Ferrer, Ph.D.		
All the surrogates that the Panel proposed are reasonable and will work well when assessing the treatment process performance. Also these surrogates should be monitored on a regular basis to ensure proper functioning of the treatment operation, especially dissolved or total organic carbon.	Acknowledged.	None
Michael D. Collins, Ph.D.		
The Reviewer does not have the expertise to theoretically predict the relative ability of the surrogate parameters to qualitatively and quantitatively reflect the changes in the concentrations of the CECs. However, the proposed surrogates for landscape irrigation appear to be targeted toward microbiological endpoints. As stated in the Panel Report (2010), a 1998 NRC report recommended that water agencies considering potable reuse fully evaluate the public health impacts from microbial pathogens as well as chemical contaminants. It could include toxins	The Panel considered microbial risks associated with the exposure to enteric viruses and parasites via irrigation as the largest threat (albeit small) to public health. The CDPH regulatory reuse standards are arguably the most robust and stringent in the nation and have been successfully relied upon to protect public health exposure to microbial pathogens. Thus, the Panel felt that inclusion of the CDPH performance standards within Table 8.2 was appropriate and justified.	None

Comment	Response	Policy Change
released by microbes as well as spores, conidia, cysts and prions. In addition to CECs are there concerns about microbiological issues?		
Stanley B. Grant, Ph.D.		
The selection process adopted for the surrogates and indicators listed in Table 8.2 are not well justified, nor referenced relative to other sections of the Panel Report, nor the peer-reviewed literature. This may be an adequate list, but the process by which it was selected is not clear to this reviewer.	Staff disagrees with this comment. The approach is illustrated in principal in the Panel Report and more detail is provided in references cited in the Panel Report. These peer-reviewed publications are very specific regarding the suitability of certain chemicals to serve as a performance indicator.	None

Topic 6 – Validity of expected percent removal of surrogates and performance indicator CECs for a treatment process

Karl G. Linden, Ph.D.		
The performance indicators span a good range of compounds with varying removal percentages. The surrogates are listed as ammonia, nitrate, DOC and UVA for SAT and conductivity and DOC for direct injection. While these surrogates may be appropriate for SAT treatment, the surrogates for direct injection, specifically those indicating AOP treatment efficacy, do	Staff agrees although conductivity and DOC are good surrogates for monitoring performance of RO processes their not performance indication of AOPs. Also, staff agrees that measuring UVA after RO and UV/AOP treatment is challenging and would require very sensitive instruments. The Recycled Water Policy has been edited to clarify that the surrogates listed in	None

Comment	Response	Policy Change
not seem appropriate. While both conductivity and DOC would readily indicate RO performance, they do not indicate AOP performance. UVA could be a good surrogate for AOP but it is not clear how much UVA would remain in the water as an indicator after RO. The performance indicators could provide a means to indicate AOP treatment as NDMA would be transmitted through the RO and be available to AOP as an indicator.	Table 2 are not comprehensive list and other surrogates may be considered to monitor the UV/AOP units.	
Michael D. Collins, Ph.D.		
The Reviewer does not have the expertise to evaluate the validity of these estimates. Two CEC compounds appear to exhibit relatively low removal expectations. One is Nitrosodimethylamine which is a highly carcinogenic compound and the second is the artificial sweetener sucralose. The relatively low removals for these two compounds, one of which is a known to be highly detrimental to health, brings up the question of whether there are other treatment unit operations which would remove these compounds?	Sucralose is poorly removed during SAT but has no health relevance. NDMA is moderately removed by RO membranes but effectively removed during the subsequent AOP process. Note the specification in Table 6, p. 16 of the amendment that distinguish between expected removal by RO alone (25-50%) and RO/AOP (>80%).	None

Comment	Response	Policy Change
Stanley B. Grant, Ph.D.		
The expected indicator and surrogate removal rates in Table 8.2 are referenced to Drewes et al., 2008, but not described (or more importantly justified) in the text.	The key reference is provided in the Panel Report.	None

Topic 7 – Appropriateness of tiered risk quotient thresholds and corresponding degree of response for evaluating monitoring results for health-based CECs in recycled water.

Michael J. Plewa, Ph.D.		
The level of concern based on the ratio of MEC/MTL=1 to priority is consistent, rational and transparent.	Acknowledged.	None
Unknown agents Some overall toxicity metric of the recycled water and comparison against some standard may be appropriate and necessary.	Staff agrees with this comment. There is an existing Science Advisory Panel working on the developing and validating bioanalytical screening tools. The Recycled Water Panel supports the development and validation of these tools to continue.	None
Tiered risk quotient threshold does not address the adverse biological impact of CECs or byproduct mixture at any tiered level.	This the rationale for the Panel's recommendation to develop and use bioanalytical assays in conjunction with chemical analytical methods to evaluate treated waters.	None

Comment	Response	Policy Change
Information on the toxicity of individual CECs should be upgraded on a regular basis and the MEC/MTL ratio recalculated. Concerned that the level of concern could be eliminated merely altering the MTLs value.	Staff agrees with this comment. The Panel recommended routine review of the MTLs.	None
Karl G. Linden Ph.D.		
The approach presented by the panel appears appropriate and rational.	Acknowledged.	None
Imma Ferrer, Ph.D.		
No specific comments	Acknowledged.	None
Michael D. Collins, Ph.D.		
The tiered risk approach appears to be an overall reasonable approach given the current state of knowledge in the recycled water field assuming that the MLTs are appropriately determined. There is one aspect of the process that concerns the Reviewer. It is proposed that a specific CEC should be removed from monitoring after a certain number of years (three) if the MEC to MLT ratio remains below 1. The concern is that many of these CECs are continually increasing in the aquatic environment over relatively long time periods and that premature termination of	The reviewer brings up an important point. Staff agrees with this comment and it is likely that a future Panel would agree to maintain CECs on a monitoring list if they have high bioaccumulation potential.	None

Comment	Response	Policy Change
monitoring may prevent the prediction of a future risk. For example, pharmaceutical agents may be constantly increasing in the aquatic environment if their aquatic half-life is long. Thus, it may be prudent to examine the temporal profile of the MEC/MTL value for a compound prior to determining whether to terminate monitoring. For example, if compound X had an MEC/MTL value of 0.1 in the first year of monitoring, a ratio of 0.2 in the second year, and a value of 0.4 in the third year, then it may be appropriate to suggest continued monitoring over time as opposed to discontinuation. In some cases, it may be appropriate to monitor the MEC less frequently, for instance once every three or five years, as opposed to discontinuing monitoring of the compound.		
Stanley B. Grant, Ph.D.		
Perhaps this is inevitable given the qualitative nature of such recommendations, but it is not clear how very specific metrics (such as "no more than 25 percent of the samples during phase-2 monitoring exceed a MEC/MTL ratio of 0.1") were arrived at. What if 25%	The proposed assessment scheme was considered reasonable. Certainly it should be re-considered using monitoring data collected by the next Panel.	None

Comment	Response	Policy Change
of samples have a MEC/MTL much great than 1? Wouldn't that be of concern? Perhaps some tangible examples involving real monitoring data (with some cumulative probability distributions shown) would help make these thresholds seem less arbitrary.		

Topic 8 – Adequacy of monitoring frequencies for CECs and Surrogates and the phased monitoring approach.

Karl G. Linden, Ph.D.		
The program for monitoring was well thought-out and is a rational approach for the industry to move forward with confidence. For specific CECs, the ideas of an initial (quarterly) assessment phase, a baseline phase, and a standard operating plan of semi-annual or annual monitoring is adequate and not overly onerous on the utility. The surrogate monitoring plan is also sound as it exploits the possibilities of continuous monitoring for these surrogates where this is possible and reasonable, and recognizes the value in monitoring of the treatment process, as opposed to just the presence and absence of CECs.	Acknowledged.	
Imma Ferrer, Ph.D.		
All of the monitoring frequencies as presented in the Panel Report are	The main motivation to use sucralose is its role as an ideal conservative tracer, which	A footnote has been added to clarify that sucralose has been added because it is a

Comment	Response	Policy Change
reasonable and well-defined. I do not see the use of sucralose as a performance indicator as its removal is less than 25%. This means that this compound would not be a good candidate after the initial assessment monitoring phase, as stated in Attachment A of the policy: *"only the performance indicators that demonstrate measurable removal for a given process shall be candidates for use in the monitoring programs for the baseline and standard operation phases"*. According to this, this compound would not be a good candidate.	allows assessing the dilution impact from native groundwater. To have a good assessment on dilution is the prerequisite to calculate removal of biodegradable CECs during SAT.	good tracer.
Michael D. Collins, Ph.D.		
The overall process should remain flexible to capture seasonal variations and facilitating the early collection of a sufficient database to start to determine the variability of the data. The Panel Report proposed "Once every five years, one additional round of CEC monitoring should be conducted to confirm monitoring results." The meaning of this statement is not clear. So, if it is going to be followed, then there should be some guidelines regarding exactly what is going to be confirmed and how this should be done.	The Panel recommended a review of the monitoring list and approach every three years. It is anticipated that the future panel would review all of the available occurrence data, toxicity data and the analytical methods used to obtain the data to determine whether the list of monitored CECs should change.	None

Comment	Response	Policy Change
Does it mean a full scan for a wide variety of compounds, sampling on consecutive days, or taking a single sample and splitting it into two samples? It is not clear as to what is meant by "confirm monitoring results.		
Stanley B. Grant, Ph.D.		
Ideally, monitoring frequency would be based on a detailed understanding of the temporal variability associated with surrogates, indicators, and CECs. The Panel Report does not provide an analysis of such data (nor does it reference peer-reviewed publications where such analysis was carried out), and as such the recommended sampling frequencies, and phasing approach, seem ad hoc. Again, this reviewer would have benefited from seeing examples of where the variability associated with real data were used to illustrate the efficacy of the proposed approach. A minor comment: please define IPR (presumably indirect potable reuse) in the text (on page 68) and in the glossary.	IPR stands for indirect potable reuse. Any product water that is delivered from these groundwater recharge projects is a composite of different groundwater parcels representing a wide range of travel times. Thus, understanding temporal variability is less relevant for these projects, but would be more important where direct potable reuse is entertained.	None

Comment	Response	Policy Change
Topic 9 – Additional Consideration: appropriateness of alternative approach for deriving MTLs.		
Michael J. Plewa, Ph.D.		
Concern about the rigor of the Snyder et al report submitted to Water ReUse Foundation – reports may not be as rigorous as in established journals. The use of a rational platform that is applied consistently to determine the threshold of toxicological concern and/or the PNEC for the CECs is an important step in reducing the level of error associated with such literature-based calculations.	The same pharmaceutical toxicity data from Snyder et al was later published in ES&T in 2010 (Bruce, G. M., R. C. Pleus, and S. A. Snyder. 2010. Toxicological Relevance of Pharmaceuticals in Drinking Water. Environmental Science & Technology 44 (14):5619-5626). Regardless, the Panel Report provides a framework through which the State may select applicable toxicity data.	None
Degradation product may be more toxic than the parent compound. CECs having low risk may be below MTLs, while a reaction of the CEC with a disinfectants may generate a byproduct that is significantly more toxic. This chemical by chemical approach does not address these types of issues.	The panel agrees and thus has recommended the development of bio-analytical assays to be used in conjunction with chemical analytical methods.	None
The NOAEL to establish a base number for the application of uncertainty factors is reasonable, but the Panel Report does not specifically list if this approach is used only for *in vivo* or i*n vitro* data. How would the Panel recommend converting the concentration values (ppm, ppb, molar	The NOAEL was obtained from published articles and is based on human/mammalian literature. These values come from either in vitro or in vivo data, as available.	None

Comment	Response	Policy Change
unties etc.) to mg/kg/day units for application in this method to establish PNEC or TTC (threshold of toxicological concern) values?		
Derivation of the MTLs for portable water is rational, consistent and is adequate for the process.	Acknowledged.	None
Derivation of MTL of irrigation. The removal of the ingestion rate may be applicable for general public, but for landscape workers may be at heightened risk. Although non-potable landscaping water will be necessarily labeled, the practice of drinking from a hose could be sufficiently curtailed amongst this exposure population.	Aside from the CDPH regulations (Title 22) that govern labeling of recycled water applications (in several languages), the regulations specifically prohibit the use of hose bibs on recycled water systems. Further, the Panel assumed a high-end exposure rate.	None
Use of analytical chemical results for the baseline monitoring data for many CECs and the comparison of these levels to the MTLs as the first level in the decision tree in a monitoring program is an adequate method.	Acknowledged	None
The impact of mixture compounds are not taken in consideration.	The Panel did acknowledge the issue and recommended bioanalytical screening tools.	None

Comment	Response	Policy Change
Interesting exercise – Assess whether the MTLs generated using the Schriks methods for the EPA regulated drinking water for disinfection byproducts.	May be something to consider by the next Panel.	None
Attention should be given for the limitation of any scheme to develop MTLs for recycled water based on limited knowledge. Iopamidol has low toxicity, but in source water with chlorine or chloramines the compound can be transformed into high genotoxic iodinated disinfection byproducts.	Staff agrees with the concerns regarding disinfection byproducts. However, in-vivo screening data for toxicity of transformation products is limited or absent. The Recycled Water Policy will be amended every five years to consider additional research that has been conducted.	None
Richard M. Gersberg, Ph.D.		
It would be most helpful if the Final Draft Amendment included a detailed description of how the MTLs were derived for each of the four health indicators, with an explicit explanation of underlying the toxicological data for the NOELs, and the safety factors applied.	The information is provided in the Panel Report.	None
Karl G. Linden, Ph.D.		
Based on limited knowledge of toxicology, the MTLs derivation approach was sound.	Acknowledged.	None
Michael D. Collins, Ph.D.		
It is not clear to the Reviewer, but it appears that wastewater treatment includes both chlorination and advanced oxidation processes (AOP) from Section	The primary objective of chlorination is disinfection; the focus of AOP is chemical/photolytic oxidation of CECs.	None

Comment	Response	Policy Change
1.5.2 in the Science Advisory Panel Report (2010). If the goals of the two unit operations are the same, then there does not appear to be any advantage, and there may be disadvantage, to performing both processes. It would seem that ozone treatment would be an advantageous option when compared to chlorination. It would seem that ozonation of wastewater would be preferable to chlorination because the water would not have any residual oxidation capacity that may prevent it from being released to natural water sources in the environment.		
The source of 17β-estradiol in wastewater was not fully discussed. If the majority of the estrogen is excreted from the human (as described in Section 8.2), then have the analyses of wastewater attempted to isolate the natural human metabolites of 17β-estradiol? Compounds of interest could include estradiol and estrone sulfates. Are these metabolites altered in the aquatic environment? Questions regarding additional compounds that have estrogenic activity could be addressed if bioassays of estrogenicity were being used in addition to monitoring 17β-estradiol	17ß-estradiol was selected as the indicator CECs for other steroids.	None

Comment	Response	Policy Change
concentrations.		
Stanley B. Grant, Ph.D.		
Not being a toxicologist, I cannot evaluate the relative merits/demerits of the alternative approach described in Section 4.3. However, as an interested non-expert, I found the section well written and compelling.	Acknowledged	None

Big Picture

Karl G. Linden, Ph.D.		
Taken as a whole, the scientific portion of the proposed rule is state of the art and should move forward in confidence. Furthermore, the proposed draft amendment is a document that strongly draws on the Panel Report and provides a robust mechanism for monitoring of CECs in recycled water for years to come.	Acknowledged.	None
Michael D. Collins, Ph.D.		
Although not a "Big Picture" item, the Reviewer is unfamiliar with general groundwater practices, and consequently was naïve with respect to how monitoring is performed. The Scientific Advisory Panel Report (2010) stated that for	The new CDPH draft regulation only requires two months instead of six. The travel time is estimated based on hydrological models and tracer studies.	None

Comment	Response	Policy Change
groundwater recharge projects in California, the recharged water is required to remain in the subsurface for a minimum of six months prior to extrapolation. This process would provide an additional level of protection from groundwater contaminants by allowing natural attenuation to occur. How is this monitored?		
The amendment does not address whether PECs have been derived and additional literature review to identify additional CECs. In addition, the development of bioassays to monitor various biological endpoints in the wastewater treatment process (Section 6.0) is not addressed. Finally, the Panel suggests monitoring for additional CECs with insufficient MECs (Section 8.5), including 1, 2, 3-trichloropropane, hydrazine and quinolone. Thus, the Reviewer found the Panel Report was considerably more broad-based than the Attachment A proposed aims.	The development of both, PEC and bioassays were strongly recommended by the Panel.	
Stanley B. Grant, Ph.D.		
In reading the Panel Report and the proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the		None

Comment	Response	Policy Change
proposed rule not described above? Overall, the Panel Report is well written, and the recommendations seem sound and well justified. As a minor point, I found the Case Examples (Appendix F) superficial. They read like PR material, as opposed to a balanced scientific evaluation of the performance (both good and bad) of each wastewater reuse scenario. There is also little discussion of unintentional reuse (where treated wastewater discharged to a river, for example, finds its way into a drinking water distribution system). Unintentional reuse is likely a common occurrence (and probably will become more common with time in California as climate change reduces base flows in rivers), and thus intentional reuse projects should be evaluated in that context. A very good discussion of this issue appears in the latest NRC report (published in 2012) on wastewater reuse, which I notice is NOT cited in the Panel Report.	Acknowledged. Two of the NRC members also served on the Panel. The NRC report was published 18 months after the release of the Panel report.	
Taken as a whole is the scientific portion of the proposed rule based on sound scientific knowledge methods and practices? Apart from the specific issues raised	Acknowledged.	None

Comment	Response	Policy Change
above, I believe the Panel Report is scientifically sound, and relies on current knowledge of methods and practices.		
In reviewing the proposed Attachment A (draft amendment), does the proposed language adequately characterize and implement the Panel's recommendations for monitoring of CECs for recycled water use in groundwater recharge and landscape irrigation? Attachment A appears to adequately summarize the recommendations of the Science Advisory Panel.	Comment noted.	

Comments on Analytical Methods

Michael J. Plewa, Ph.D.		
A host of specific cell lines could be used to measure chronic cytotoxicity, genotoxicity, or to analyze the metabolic activation of recycled water agents (human HepG2 cells) or to determine endocrine disruption activity.	Yes, in fact there are several commercial companies in the US that offer in vitro assays that measure chemical-induced transactivation of most of the human soluble nuclear receptors. These assays must be tested for their usefulness for water testing.	None
Cell-based. Global toxicity analyses require concentration of chemicals present in	Extraction methods for water are being developed for in vitro based assays.	None

Comment	Response	Policy Change
water. This could be done through lyophilization, reverse osmosis, liquid-liquid extractions, activated carbon, XAD resin, and ion exchange. Using resin-based concentration methods, an adequate sample of recycled water could be efficiently processed and concentrated for *in vitro* analyses.		
In vitro bioassays of a concentration recycled water sample would provide a baseline value for the entire mixture of contaminants in the recycled water before and after treatments. Could directly compare the overall toxicity of the recycled water sample to a known regulated standard such as a DBP regulated by EPA.	Extraction methods for water are being developed for in vitro based assays.	None
In vitro bioassays of a concentration recycled water sample would provide a baseline value for the entire mixture of contaminants in the recycled water before and after treatments. Could directly compare the overall toxicity of the recycled water sample to a known regulated standard such as a disinfection byproduct regulated by EPA.	The recommendation is to develop in vitro bioassays to go along with analytical chemistry methods to determine the occurrence and toxicity of water samples.	None

Comment	Response	Policy Change
Imma Ferrer, Ph.D.		
The methods required to monitor for these CECs involve LC-MS with triple quadrupole mass spectrometry, which can easily reach the 1-10 ng/L level in all cases, with perhaps the exception of 17-ß-ethinylestradiol, which is much more difficult to measure at these low levels. Thus, the idea to substitute estrone was suggested in order to easily reach the 1 ng/L limits of detection.	Staff agrees with the comment in principal, but estradiol was considered to have a higher human health risk than estrone.	None
The four indicator compounds would require two methods, a GC-MS high resolution method for NDMA and a LC-MS-MS method for 17-ß-ethinylestradiol (negative ion), carbamazepine (positive ion), and sulfamethoxazole (positive ion). Given that the cost of analysis for LC-MS-MS involves the same procedure, it seems like a good idea to monitor at least 10 to 15 more analytes as part of this method. Why not gain as much information as possible? Why only four analytes, when it is possible to have 20 analytes at the 1 ng/l level for water reuse and indicator compounds? This would give a much better idea of what is in the water and how the compounds are being removed. My fear is that the original	Staff agrees with the comment in principal. While more information could be gained from multi-chemical analytical methods, the results would not necessarily result in more insight if the CECs targeted do not represent different classes or groups of chemicals responding differently to a given treatment process.	None

Comment	Response	Policy Change
four compounds will give many non-detections and nothing much will be learned from these negatives for water treatment studies. A longer list of 20 compounds would be quite easy to setup and monitor for the same cost. We routinely look at more than 20 compounds (CECs) at the 1-10 ng/l level using LC-MS-MS and these data are quite helpful in understanding sources and movement of CECs in the environment.		

Specific Comments

Karl G. Linden, Ph.D.		
Page 2 of the amendment – "AOPs are treatment processes involving the use of hydrogen peroxide and ozone; commonly combined with ultraviolent light irradiation. This is not completely correct. AOPs typically are either UV/H_2O_2 or ozone/H_2O_2. Ozone/UV and ozone/ H_2O_2/UV are also AOPs but are rarely used in recycled water applications. So saying they are commonly combined with ultraviolet light irradiation is not correct. The most common AOP used in the water industry is UV/H_2O_2 advanced oxidation, such as in the Orange County GWR project. It was my understanding that this technology, preceded by RO, was the	Acknowledged.	Policy change to correct the description.

Comment	Response	Policy Change
treatment train used for direct injection according to the Policy under review.		
Amendment – Table 1. The reporting limits noted may be temporal – they may improve with time. Is there a means to address the changes in analytical chemistry that could affect the levels of reporting and how low would it have to be for it to be inconsequential	This should be considered during the regular five year review by the Panel.	None
It is stated that the list of health-relevant CECs for monitoring may be revised based on baseline monitoring results. Is there a process for this? What would trigger a revision? Would it go back to the universe of chemicals or just evaluate single chemicals? How would new chemicals be identified if only the listed ones are being monitored for?	The recommended five year review by a Panel will address these issues.	None
Surrogates. The discussion about surrogates on Page 5 says surrogates should be based on the types of treatment used. It would make sense then to indicate for the surrogates listed in Table 2, what treatment processes they can be used for.	This is indicated in the Panel Report (Table 8.2, p. 66) and the draft amendment (Table 6, p. 16).	None
Performance Indicators (Page 9).	See comment above. The performance	None

Comment	Response	Policy Change
Performance indicators detected during the initial monitoring phase should be used in the baseline monitoring phase. These performance indicators may or may not be the best for monitoring of treatment processes. It may be better to require specific performance indicator(s) that are known to be relevant for a given treatment process.	indicators are only suitable for the two types of groundwater recharge practices listed.	
Monitoring Framework. It may be instructive to have a flow chart for the monitoring framework.	See Figure 8.1 in the Panel Report.	None
Attachment A -Table 4. All CEC and indicators analysis are measured semi-annually – could there be any seasonality to the presence of CECs or performance indicators? How would this be captured	The seasonal effect for permitted groundwater recharge projects is minimal in Southern California.	None
Is the monitoring phase specifically to correlate the surrogates and CECs or performance indicators? The section on pages 66-67 (Panel Report) suggests that differentials should be documented during monitoring and somewhat implies that there is more to learn during the monitoring phase about how surrogates and	The State Water Board/CDPH and the project proponent need to work closely together in order to tailor a monitoring program for a given project.	None

Comment	Response	Policy Change
performance indicators correlate for removal during treatment. Yet the Table 8.2 specifies surrogates and indicators and percent removals expected. To what extent is this process an iterative process as more is learned? I believe the approach is healthy for the industry but the specific intent was not very clear.		
AOP definition. The amendment continually refers to "AOPs". However, there are many types of AOPs. Page 2 refers to ozone, peroxide, and UV combinations. The draft criteria as quoted in Appendix C of the Panel Report, specifies UV/AOP for direct injection applications. It would be helpful to clean this up and specifically state what types of AOP are acceptable and if it is only UV/H_2O_2 AOP then it should be stated specifically	The Policy applies to advanced oxidation processes that employ ultraviolet radiation.	Edit made to section 1, third paragraph.
Imma Ferrer, Ph.D.		
Charge 3 - Would the above lists of constituents change based on level of treatment and use? If so, how? The eight CEC compounds would change based on the type of treatment applied. For	Yes. See comments above.	None

Comment	Response	Policy Change
example, simple sand filtration would not be effective for all eight of the compounds, at least with respect to sorption and biodegradation. Bank filtration studies show that the compounds are mobile in sand columns with only a slight chance of biodegradation, less than 5% degradation. On the other hand, carbon filtration is highly effective for 6 of the eight compounds, only caffeine and sucralose would have rapid breakthrough on fresh carbon, based on our studies in the laboratory and my experience with solid phase extraction of these compounds, i.e. hydrophobicity and sorption potential. I am not experienced with advanced oxidation processes for these compounds. This would require a literature search for all 8 compounds.		
Charge 5 - What levels of CECs should trigger enhanced monitoring of CECs in recycled water, groundwater, and/or surface waters? It is not so much the level of CECs that should trigger enhanced monitoring but the number of compounds that are present. It is not uncommon for example to find both caffeine and sucralose in drinking water	Acknowledged.	None

Comment	Response	Policy Change
sources, especially reservoirs that have other activities, such as recreation. In these cases, we suspect that beverages and soft drinks may well be the source of these compounds at trace levels that is from 10-50 ng/L. Since both of these compounds are being considered by the State of California, it is imperative to understand that a suite of compounds may be much more important. Finding only sucralose and caffeine (which are part of our suite) are not a cause for concern. However, in nearby streams and canals that we monitor we find a suite of CECs, from 5 to 10 compounds, mostly pharmaceuticals. This raises a red flag suggesting that further and more frequent monitoring may be necessary. Also it is important to consider looking for non-targeted compounds, what the Panel refers to as unknown unknowns. This is a good idea and requires other types of instrumentation, such as LC/Q-TOF-MS, the use of databases, and GC/Q-TOF-MS, also using databases. This type of monitoring would be worth considering by the State of California because there may be many CECs that are present. Scans of accurate mass could be used both before		

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and after treatment or archived for future use. It is important to realize that state-of-the-art mass spectrometry is currently available for use on this project and should not be forgotten. The Panel does not discuss these methods in the Panel Report.		
There is no mention of trace metals, mainly arsenic and selenium, which are known water quality problems in California, especially for irrigation purposes.	These are regulated in California and not considered CECs.	None
Health Relevant CECs N-Nitrosodimethylamine (NDMA) merits its selection on the list as the first and most important compound for monitoring based on toxicity. I definitely agree that this compound should be chosen for future monitoring based on toxicity and it does represent a class of chlorinated N-nitrosoamines of interest of which there are at least 7 compounds that have been reported. A limit of detection (LOD) of 1 ng/L should be adequate for a monitoring study of this compound in groundwater and reuse waters.	Acknowledged.	None
Health Relevant CECs 17ß-Estradiol (E2) is not a good CEC and should be replaced by a more estrogenic,	Staff disagrees with this comment. The occurrence of EE2 in recycled water in	None

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man-made pharmaceutical hormone, 17-□-ethinylestradiol (EE2). EE2 is the compound that would be most important to monitor since it is not a natural compound, it is used in the birth control pill (a pharmaceutical and a potent endocrine disruptor); thus, it would be a much better choice than the 17-ß-estradiol. This compound has generated a tremendous amount of literature over the past 12 years on endocrine disruption, especially in fish. The same methods available for E2 will work equally well for EE2, a suggestion is LC-MS-MS in negative ion mode. Further, I would suggest the addition of estrone as an indicator compound as well to go along with the EE2. The reason being that it will occur at higher concentration levels based on both our experience and that which is shown in Appendix K and that its removal should mimic EE2 and E2 giving confidence to treatment procedures. The fact that E2 is produced naturally in the body of both men and women at levels considerably greater than what appears to occur in wastewater, it seems more relevant to select EE2 as a toxic indicator compound over E2. Furthermore, the fact that E2 occurs naturally in our bodies it is difficult to	almost all cases is below the detection limit.	

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call this a CEC, whereas EE2 definitely fits the description of a CEC of highest toxic concern.		
Health Relevant CECs Caffeine is a very poor choice and should definitely be replaced by another psychoactive compound, such as carbamazepine. This is a ridiculous compound to be monitoring under the CEC list of toxic compounds. This highest value is more than 10,000 lower than a Coffee Americano and 150,000 lower than my double espresso. It is not on the same toxic par as NDMA or EE2, not in any shape or form. Furthermore, it does not represent a class of compounds reported. The only other compound similar is it's degradate, 1, 3-dimethylxanthine, which is not a compound typically on the CEC list. Rather, it is the human metabolite of caffeine. Furthermore, caffeine has other sources than wastewater, i.e. food and drinks. Finally, it does degrade in the body and would not be a good tracer for groundwater recharge. I highly think that this compound should be removed from the list and another more relevant compound substituted. Carbamazepine occurs at a	The logic for the selection of caffeine is described in the Panel Report in detail. Australia published a health-based standard which the Panel adopted.	None

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median level of 200 ng/L similar to caffeine (Appendix K), is known to be present in all wastewaters, and is relatively toxic. None of the four compounds are pharmaceuticals, including triclosan. Carbamazepine works quite well by LC-MS-MS in positive ion mode with detection limits in the 1-10 ng/l range		
Health Relevant CECs Triclosan is a poor choice also for an antimicrobial and should be replaced by sulfamethoxazole. A quick literature survey shows that triclosan was considered a safe compound (Bhargava et. al. 1996) and more recently triclosan levels in mother's breast milk was not considered toxic to infants (Dayan, 2007). Therefore, the selection of this compound for monitoring on toxicity basis seems weak. Also in our experience, triclosan is detected much less frequently than many CECs and has a strong sorption to soil and presumably to aquifer solids. Thus, it should show removal in groundwater. It does not represent a class of compounds, as this is the only CEC of this type. Thus suggest that this is not a good choice for a health relevant compound. Both sulfamethoxazole and trimethoprim are found ubiquitously in	SMX was evaluated but did not trigger a MTL.	None

Comment	Response	Policy Change
reuse water and much higher median concentrations, i.e. 295 ng/L for sulfamethoxazole and 44 ng/L for trimethoprim. These two compounds are widely used and sulfamethoxazole represents a large class of antibiotics. LC-MS methods using triple quadrupole are available at the 1-10 ng/L level, which are entirely suitable for these compounds.		
The CECs chosen by the State of California should include man-made pharmaceuticals and man-made hormones, which the four compounds chosen are not.	Staff disagrees with this comment. The basis for this comment is not provided.	None